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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,657	12/13/2005	Carl-Johan Aureli	101078 - 1P US	2259
52286 COZEN O'CON	7590 02/15/2007 NOR, P.C.		EXAMINER	
1900 MARKET STREET PHILADELPHIA, PA 19380		•	VALENROD, YEVGENY	
			ART UNIT	PAPER NUMBER
			1621	
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SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS		02/15/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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	Application No.	Applicant(s)				
Office Action Summany	10/560,657	AURELL ET AL.				
Office Action Summary	Examiner	Art Unit				
	Yevgeny Valenrod	1621				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on						
· · · · · · · · · · · · · · · · · · ·	action is non-final.					
3) Since this application is in condition for allowar	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4) ☐ Claim(s) 1-7 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-7 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or election requirement.						
Application Papers	•					
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)	•					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/13/05.  S. Patent and Trademark Office						

Application/Control Number: 10/560,657

Art Unit: 1621

## **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindstedt et al. (US 2005/0171204).

Instant claims are directed to amine salts of (2S)-2-ethoxy-3-(4-{2-[hexyl(2-phenylethyl)-amino]-2-oxoethoxy}phenyl)propanoic acid (from now on Compound I). Specific amine salts are claimed in claims1-4. Claim 5 is directed to a salt which is a hydrate, solvate or mixed. Claims 6 and 7 are directed to crystalline or partially crystalline forms of the salt.

## Scope of prior art

Lindstedt et al. teach the free acid of compound 1 (page 2, paragraph [0021]).

They also teach ammounium and basic amino acid salts of the free acid acid

(paragraph [0023], line4) and crystalline forms (paragraph [0022]). In paragraph [0024],

lines 1-3, Lindstedt et al. teach the hydrated form of the compound.

Ascertaining the difference between prior art and the instant claims

Lindstedt et al. teach ammonium salts of the free acid of compound I. However they do not teach the specific ammonium salts found in claim 1.

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## **Obviousness**

Ammonium salts of pharmacologically active compounds are common in the art. Lindstedt et al. broadly teach salts of the compound of formula I and specifically mention ammonium salts. The instant invention claims particular ammonium salts. The claimed salts are not patentable over Lindsdedt et al. absent unexpected results arising from the use of specific ammonium counterions listed in the claims. In the specification, on page 2, applicant compares the compounds of the instant invention to those found in PCT/GB02/05743. The alleged unexpected result of the ammonium salts claimed by the applicant, is that it can be made into a crystalline form. Examiner would like to note that the compounds of PCT/GB02/05743 are structurally different from those of the instant invention. Therefore, the alleged unexpected result is not applicable to the instant case. In order to claim unexpected result the applicant needs to supply evidence that would make clear what advantage the ammonium salts of compound I claimed by the applicant have over the salts described by Lindstedt et al.

#### Conclusion

Claims 1-7 are pending

Claims 1-7 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yevgeny Valenrod

Patent Examiner

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